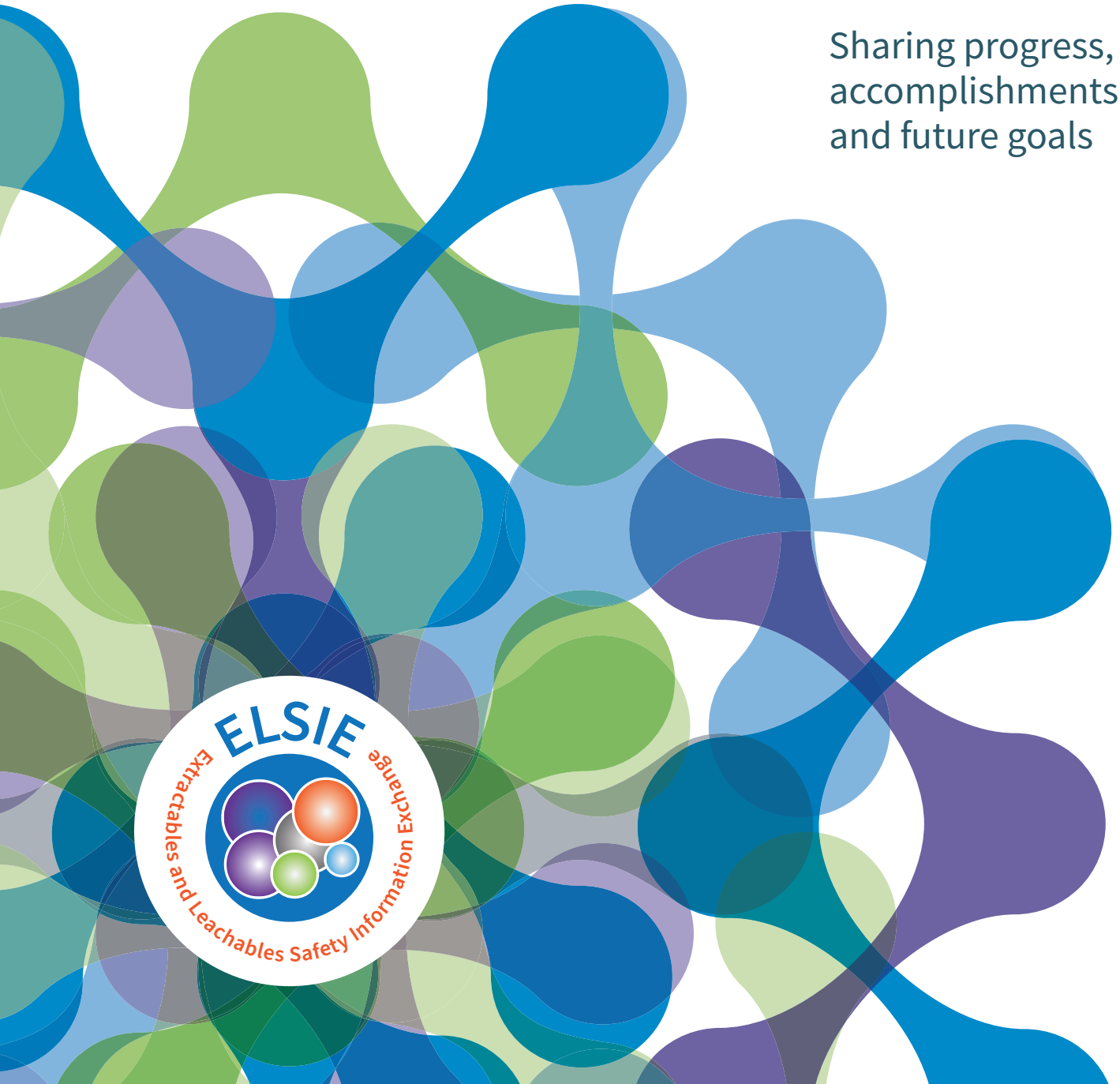
ELSIE 2021

YEAR IN REVIEW

Sharing progress, accomplishments and future goals



Reflections from ELSIE Chair

Uma Bruen, PhD (Organon)

Reflecting on 2021 is not easy. For many of us, it was the hope of coming out of the pandemic that kept us optimistic of what we could accomplish. We were finally able to see some of our family, friends, and colleagues, while continuing to take needed precautions. Many of us are still feeling stretched with duties as we continued to change and adapt and find "new ways of working."

As I reflect on what inspired me this year, it is the wonderful and brilliant ELSIE members with whom I have collaborated to progress science within the E&L arena. This is what keeps me moving forward -- the pursuit of improved understanding. It is phenomenal what we have accomplished in 2021. In the following pages you will see some of our collective key achievements.

I am optimistic and excited about the new year, with hopes of finally traveling to see colleagues, share ideas, and celebrate all that we have accomplished over the past year. I look forward to new endeavors in 2022. The ELSIE consortium will continue to provide valuable guidance in a range of areas, including constructively supporting ICH Q3E efforts and implementation of the innovative Knowledge Base. We will focus on new ways to evaluate E&L, such as predictive modelling with an eye towards pragmatic validated industry models and focusing on E&L issues in medical devices, and as always, we will strive to stay ahead of the evolving science. The members of the ELSIE consortium are all "Rock Stars"! Thank you.

Constructively Influencing the E&L Landscape

Initiated an interactive webinar series, attended by international regulators, industry, and suppliers, to discuss ELSIE's position papers on a leachables risk management framework, including an in-depth case study. These papers provide a framework for the evaluation and management of E&Ls at all stages.

Monitored and reported on developments within ICH, ISO, USP, NMPA China, FDA, and PQRI.

Advancing the Science of E&L

Developed two key scientific papers of high interest to industry and regulators (both under journal review): (1) a data-based proposal for thresholds of toxicological concern and (2) a framework and proposal for sensitization risk assessment.

Developing a manuscript on better understanding and managing the risks of leachables related to new modalities, particularly cell and gene therapies.

Understanding and progressing the current state of leachables migration modeling and creating pathways to engage regulators on use and acceptance of modeling.

Building a Powerful, Novel Next Generation Database

Driving the final development stages of the ELSIE Knowledge Base – a relational database that will allow users to access extractables and leachables toxicity information and extraction study results, as well as link material, chemical and toxicity information.

Expanding existing Safety Database and responding to ELSIE members' needs for emergency Safety Reports.

Implementing a systematic approach for deriving PDEs and adding them to the ELSIE database, creating a valuable research tool and reference for members.

Collaborating Across the Broader E&L Community

Participating in discussions with FDA CDRH on development of migration modelling approaches.

Inviting thought leaders in E&L to discuss emerging topics with consortium membership.

Presenting at numerous leading conferences.

ELSIE at 2021 Conferences

Informa Markets E&L Virtual Conference 2021 • 3 - 4 March

PITTCON Virtual Conference • 10 March

Extractables and Leachables for Pharma Summit • 19 - 20 May

Volanthen Group 2nd Extractables and Leachables Live Event • 9 June

E&L USA • 28 June - 1 July

E&L Europe • 17 - 18 November

E&L China • 23 - 24 November

ELSIE Webinars

Leachables Risk Management Webinar • 25 May

Leachables Risk Management Case Study Webinar • 29 September

A Deeper Dive on a Few of **ELSIE's 2021 Accomplishments**

Despite the COVID-19 pandemic, ELSIE has made excellent progress on the **Knowledge Base** project – a next generation database for organizing safety/toxicology and extractable data. A small, agile team of ELSIE representatives along with the Secretariat continue to work with the Knowledge Base vendor to support their development efforts. With the completion of the Knowledge Base user interface design, refinement of the data model and data import templates, and the safety and extractables report functionality defined, the Knowledge Base has fully entered the software development phase and is expected to go-live in Q3-2022.

ELSIE established a team to develop data-based proposals for **thresholds of toxicological concern (TTC)** for extractables and leachables. This team reviewed and analyzed safety data for nearly 500 compounds in the ELSIE Safety Information Database to derive parenteral TTC values for organic, non-mutagenic E&L substances when administered parenterally. Their findings are reported in a pending publication, and the group is currently pursuing further work. Taken together, this group is advancing knowledge in the E&L space by clarifying and providing a science-based TTC approach for industry and regulatory consideration and use.

ELSIE established a **sensitization assessment framework and developed best practices for sensitization risk assessment**. ELSIE members extracted and evaluated sensitization data from safety reports in the ELSIE database and developed a qualitative risk assessment approach for weak and moderate sensitizers. This framework is reported in an ELSIE paper (pending publication) that provides an overview of dermal, respiratory, and systemic sensitization and its relevance for extractables and leachables.

ELSIE is leveraging its diverse membership to address the growing areas of **leachables related to new drug product modalities**. These products present novel paradigms of manufacture and drug delivery to patients, and thus present novel risks related to leachables. ELSIE is developing a paper that will illustrate these new manufacturing process paradigms and the areas of leachables risk associated with them, and provide insights into how industry can manage these risks. This is an on-going emerging topic for both industry and regulators. No published guidance or best practices addressing this topic exists – a significant gap that ELSIE seeks to fill with this planned publication.

ELSIE has established a **medical devices discussion group**, which will provide members with a collaborative platform for sharing questions, challenges and solutions. ELSIE established this group in response to members' interest and need to better understand how to address evolving and disparate global leachables management requirements. The group is progressing ELSIE's mission of knowledge sharing to help members address pressing and complex issues.

Congratulations

to Brad Standard, PhD (Ultragenyx) for receiving the **2021 ELSIE Chair Award** for his outstanding leadership and many contributions to ELSIE.

ELSIE **Members**

AbbVie
ACS Dobfar*
Aguettant*
Amgen
AstraZeneca
Baxter
Biogen
Bristol Myers Squibb
Boehringer Ingelheim
Bracco*
Elanco
Eli Lilly and Company
EMD Serono
Genentech/Roche
Gilead Sciences
GlaxoSmithKline
Johnson & Johnson
LFB
Merck
Moderna*
Novartis
Novo Nordisk
Organon
Pfizer
Sanofi
Teva
Ultragenyx
Xellia

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